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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,154	09/20/2005	Margaretha Grind	056291-5256	1056

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EXAMINER	
AUDET, MAURY A	
ART UNIT	PAPER NUMBER
1654	
MAIL DATE	DELIVERY MODE
09/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,154	GRIND, MARGARETHA	
	Examiner	Art Unit	
	MAURY AUDET	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,16 and 18-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,16 and 18-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *9/20/05* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

As indicated previously, the present application has been transferred from former Examiner Khanna to the present Examiner.

Applicant's amendment and response are acknowledged.

It was not readily apparent what the real issue of the claimed invention was, based on the previous Examiner's approach to examining the claimed invention, via art under 35 USC 102. The art rejection however was not maintainable, at a minimum, in this Examiner's view, because of Applicant's expressly claimed limitation that a "cholesterol-lowering amount" of melagatran had to be administered. However, after further review, the real issue falls under 35 USC 101, Lack of Utility, as expounded on below.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 14, 16, and 18-21 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility (or at a minimum a well established utility).

The 3-prong test for whether a claimed invention has utility is that it must be specific, substantial, and credible. Here, the utility is deemed to be specific, questionably substantial, but fails as a credible utility, because the test data relied upon was run against a Non-Control - another compound (warfarin, also known as an anticoagulant) also not known to be a cholesterol-lowering agent, the asserted utility of the claimed invention.

Although Applicant has "asserted" a new "potential utility" (description page 18, last para) of melagatran as a cholesterol-lowering therapy and method thereof, the claimed invention is not in fact deemed to have utility for such or at a minimum a well established utility, based on the support within the description.

Thus the present 'potential utility' can only be deemed to be theoretical, at best, since the test was run against an agent that cannot be deemed a "control", warfarin, because the latter is not known to be a cholesterol-lowering agent.

[NOTE: A coextensive 35 USC 112 1st Enablement rejection has not be made, because technically Applicant's description provides that, at least in the comparison against warfarin, also having a known, established utility as an anticoagulant, the test data indicates that melagatran is arguably enabled to lower cholesterol MORE THAN it's similarly functioning warfarin].

The present description (page 18-20, Figures 1-4) has described test data showing melagatran lowers cholesterol more than the control, warfarin. However, the test is flawed, because warfarin is known or established to be a cholesterol-lowering agent and therefore cannot serve as a "control" for comparison.

As noted in Wikipedia, warfarin is known to be an anticoagulant (http://en.wikipedia.org/wiki/Warfarin, last modified on 20 September 2009):

Therapeutic uses

Warfarin is prescribed to people with an increased tendency for thrombosis or as secondary prophylaxis (prevention of further episodes) in those individuals that have already formed a blood clot (thrombus). Warfarin treatment can help prevent formation of future blood clots and help reduce the risk of embolism (migration of a thrombus to a spot where it blocks blood supply to a vital organ). Common clinical indications for warfarin use are atrial fibrillation, the presence of artificial heart valves, deep venous thrombosis, pulmonary embolism, antiphospholipid syndrome and, occasionally, after heart attacks (myocardial infarction).[19]

[Dosing]

In some countries, other coumadins are used instead of warfarin, such as acenocoumarol and phenprocoumon. These have a shorter (acenocoumarol) or longer (phenprocoumon) half-life, and are not completely interchangeable with warfarin. The oral anticoagulant ximelagatran (trade name Exanta) was expected to replace warfarin to a large degree when introduced; however, reports of hepatotoxicity (liver damage) prompted its manufacturer to withdraw it from further development. Other drugs offering the efficacy of warfarin without a need for monitoring, such as dabigatran and rivaroxaban, are under development.[12]

There is no public record/acknowledgement of warfarin's utility as a cholesterol-lowering agent.

Two references, additionally cited merely for illustration, indicate both melagatran and warfarin are known for having utility as anticoagulants, see Dugger, III (US 2003007729) claims 14, 37, 55, and 81; and Laughlin et al. (US 20050069527 A1) claim 55.

By analogy, the "potential utility" asserted by the test data of melagatran v. warfarin (a NON-control for study purposes), both anticoagulants and not known as cholesterol lowering agents, is the same "potential utility" that could have been asserted for Michael Jordan as a bona-fide Major League Baseball Player v. a control group of other NBA basketball players. Against other NBA players there is no doubt that Michael Jordan's stat's on the baseball diamond may have looked real good against other Non-Control NBA basketball players, if compared there against. However, when Michael Jordan was tested for his utility as a baseball player, against even Minor League Baseball Players, few of whom were at the quality of Major League Baseball Players, he was found even at this level to not have realistic utility as a Major League Baseball Player, with a batting ave. of somewhere between .185 - .220 only. His utility against real Control's at the Major League level, can only be presumed to have been less.

Michael Jordan put forth a specific and substantial desire to have utility as a Major League Baseball Player, but he was not found to be credible; credibly suited to have utility in MLB (as opposed to a few other cross-over athletes, who were able to establish their credibility against legitimate 'controls' at the AAA minor league level and Major League levels; such as NBA basketball player Danny Ainge in the '70's/'80's and NFL football player Bo Jackson during the '80's/'90's).

Absent evidence to the contrary of further testing and data against actual cholesterol-lowering agents 'credible' as 'control's (beyond warfarin, a non-control anticoagulant), the presently claimed invention of melagatran as a cholesterol-lowering agent, is not deemed to have credible utility. And as such, would not be useful or find utility for such a purpose in the open market v. other cholesterol-lowering agents that have been tested against credible controls and found to be credibly useful therefor.

Claim Rejections - 35 USC § 112 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18-21 recites the limitation "prodrug" in lines 2 (or dependent thereto). There is insufficient antecedent basis for this limitation in the claim, as base claim 1 has deleted reference to prodrug to traverse the 112 1st Written Description Rejection.

The 112 1st Written Description rejection has been dropped, because it is believed this was an inadvertent oversight by Applicant.

Claim 18 to any prodrug needs to be cancelled.

However, the Examiner is open to claims 19-21 being amended into base claim 14, as the prodrug therein, has been distinctly and expressly claimed.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA, 9/20/09

/Maury Audet/
Examiner, Art Unit 1654
Full Sign. Auth. Program